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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,638	09/09/2003	William D. Lakin	02962-00062	4716
21918	7590	06/17/2005	EXAMINER	
DOWNS RACHLIN MARTIN PLLC 199 MAIN STREET P O BOX 190 BURLINGTON, VT 05402-0190			SAADAT, CAMERON	
		ART UNIT	PAPER NUMBER	
		3713		

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,638	LAKIN ET AL.	
	Examiner	Art Unit	
	Cameron Saadat	3713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 3/8/2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-38 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-38 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 09 September 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/22/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In response to preliminary amendment filed 3/8/2005, claims 1-38 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 13 and 30, the phrase "wherein the plurality of compartments include a rest of body compartment" is vague and unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 12-26, 29-36, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Page (USPN 5,199,877).

Regarding claims 1, 18, 36, and 38, Page discloses a system and method of modeling pressure dynamics of a body's intracranial system comprising the steps of: dividing the body into a plurality of compartments and a heart pump 30, each of the plurality of compartments representing a portion of the body, the heart pump interacting with at least one of the plurality of compartments (Col. 2, lines 37-65); deriving a plurality of differential flow equations, each of

the plurality of differential flow equations corresponding to one of the plurality of compartments; and solving the plurality of differential flow equations (Col. 3, lines 1-35).

Regarding claims 2 and 19, Page discloses a method wherein at least one of the differential equations accounts for cerebrovascular autoregulation by the body's sympathetic nervous system (Col. 10, lines 45-55).

Regarding claims 3 and 20, Page discloses a method wherein the plurality of compartments include a plurality of vascular compartments (Col. 2, lines 37-66).

Regarding claims 4 and 21, Page discloses a method wherein the plurality of vascular compartments include a plurality of intracranial compartments (Col. 2, lines 37-66).

Regarding claims 5 and 22, Page discloses a method wherein the plurality of intracranial compartments represent at least one of the intracranial arteries, intracranial capillaries, choroids plexus capillaries, venous sinus jugular veins, and intracranial veins (Col. 2, lines 37-66; Col. 6, lines 12-35).

Regarding claims 6 and 23, Page discloses a method wherein the plurality of vascular compartments include a plurality of central body compartments (Col. 2, lines 46-50).

Regarding claims 7 and 24, Page discloses a method wherein the plurality of central body compartments represent at least one of the central arteries, central capillaries, central veins, and extra-ventricular CSF (Col. 2, lines 37-66).

Regarding claims 8 and 25, Page discloses a method wherein the plurality of vascular compartments include a plurality of lower body compartments (Col. 5, lines 35-42).

Regarding claims 9 and 26, Page discloses a method wherein the plurality of lower body compartments represent at least one of the lower arteries, lower capillaries, and lower veins (Col. 5, lines 35-42).

Regarding claims 12 and 29, Page discloses a method further comprising an atmosphere compartment, the atmosphere compartment representing a space located outside the body (Col. 1, lines 58-62).

Regarding claims 13 and 30, Page discloses a method wherein the plurality of compartments include a rest of body compartment (Col. 1, lines 58-62).

Regarding claims 14 and 31, Page discloses a method wherein the plurality of differential flow equations simulate the pressure dynamics of the body's intracranial system (Col. 11, line 20 – Col. 12, line 68).

Regarding claim 15, Page discloses a method wherein the plurality of differential flow equations include a pressure driven flows equation (Col. 11, line 20 – Col. 12, line 68).

Regarding claims 16 and 32, Page discloses a method wherein the plurality of differential flow equations include an equation simulating fluid filtration from capillaries into interstitial space (Col. 2, lines 60-66).

Regarding claims 17 and 33, Page discloses a method wherein the plurality of differential flow equations include an equation simulating deformation of the membrane between adjacent compartments (Col. 9, lines 33-68).

Regarding claims 34 and 35, Page discloses a method of modeling pressure dynamics of an intracranial system comprising the steps of: dividing a body into a plurality of compartments and a heart pump 30, each of said plurality of compartments representing a portion of the body,

the heart pump interacting with at least one of said plurality of compartments (Col. 2, lines 37-65); deriving a plurality of differential flow equations, each of the plurality of differential flow equations corresponding to one of the plurality of compartments (Col. 3, lines 1-35), wherein at least one of the differential flow equations accounts for cerebrovascular autoregulation by a sympathetic nervous system; and solving said plurality of differential flow equations (Col. 10, lines 45-55).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-11 and 27-28 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Page (USPN 5,199,877).

Regarding claims 10 and 27, Page discloses a method wherein the plurality of compartments include a non-vascular compartment comprising a tumor (Col. 9, lines 19-22). Page does not explicitly disclose that there is a plurality of non-vascular compartments.

However, it is the examiner's position that it would be obvious to one of ordinary skill in the art to modify the non-vascular compartment described in Page by providing a *plurality* of non-vascular compartments, in order to simulate physiological events which occur during the growth of multiple brain tumors.

Regarding claims 11 and 28, Page discloses a method wherein the plurality of non-vascular compartments represent at least one of the lower tissue, brain, ventricular CSF, and extra-ventricular CSF (Col. 9, lines 19-60).

Regarding claim 37, Page discloses a method of modeling pressure dynamics of a body's intracranial system comprising the steps of: dividing the body into a plurality of compartments and a heart pump 30, each of said plurality of compartments representing a portion of the body, said heart pump interacting with at least one of said plurality of compartments (Col. 2, lines 37-65), wherein a plurality of said plurality of compartments are vascular (Col. 2, lines 37-66) and a compartment that is non-vascular (Col. 9, lines 19-22), the vascular compartments including at least one of the intracranial arteries, intracranial capillaries, choroids plexus capillaries, venous sinus jugular veins, intracranial veins, central arteries, central capillaries, central veins, extra-ventricular CSF, lower arteries, lower capillaries, and lower veins, the non-vascular compartments including at least one of lower tissue, brain, ventricular CSF, and extra-ventricular CSF; deriving a plurality of differential flow equations, each of said plurality of differential flow equations corresponding to one of said plurality of compartments; and solving said plurality of differential flow equations (Col. 10, lines 45-55). Page discloses all of the claimed subject matter of claim 37 with the exception of explicitly disclosing that there is a plurality of non-vascular compartments. However, it is the examiner's position that it would be obvious to one of

ordinary skill in the art to modify the non-vascular compartment described in Page by providing a *plurality* of non-vascular compartments, in order to simulate physiological events which occur during the growth of multiple brain tumors.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Van Meurs et al. (USPN 6,273,728) – disclose a simulation system for simulating human physiological parameters.
- Le Roy (USPN 4,003,141) – discloses an intracranial pressure monitoring device for monitoring pressure in a simulated skull.
- Thoman, William James (A computer Model of Intracranial Dynamics) – discloses a software model of intracranial dynamics.
- Wang, Eryu (A model of the Dynamics of Intracranial Pressure During Conditions of Intact and Loss of Cerebral Vascular Tone) – discloses a mathematical model to simulate the dynamics of intracranial pressure and cerebral blood flow.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cameron Saadat whose telephone number is (571) 272-4443. The examiner can normally be reached on M-F 9:00 - 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on (571) 272-7147. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3713

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cameron Saadat
June 9, 2005



XUAN M. THAI
SUPERVISORY PATENT EXAMINER
TC3700